



February 23, 2022

Greer Massey, Ph.D.  
Assurance Scientific Laboratories  
2868 Acton Road  
Birmingham, AL 35243

Device: Assurance SARS-CoV-2 Panel

EUA Number: EUA200522

Company: Assurance Scientific Laboratories

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal or oropharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider.

This test is also intended for use with anterior nasal swab specimens that are collected using the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to laboratories designated by Assurance Scientific Laboratories that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Dear Dr. Massey:

On May 15, 2020, based on your<sup>1</sup> request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Assurance SARS-CoV-2 Panel for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal or oropharyngeal swabs from individuals suspected of COVID-19 infection by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The May 15, 2020, letter authorizing emergency use of this test, also authorized its use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit specified in this authorized test's authorized labeling, when determined to be appropriate by a healthcare provider. Testing was limited to Assurance Scientific Laboratories that is certified under the Clinical Laboratory Improvement

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<sup>1</sup> For ease of reference, this letter will use the term "you" and related terms to refer to Assurance Scientific Laboratories.

Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Based on your request, the May 15, 2020, letter was revised and reissued by FDA on August 19, 2020<sup>2</sup> and June 3, 2021.<sup>3</sup> Based on your request, FDA also granted updates to the authorized labeling on September 21, 2020.<sup>4</sup>

In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.<sup>5</sup>

On February 7, 2022, you requested to further revise your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the June 3, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the June 3, 2021, letter in its entirety with the revisions incorporated.<sup>6</sup> Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product<sup>7</sup> is now intended for the indications described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of

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<sup>2</sup> On August 19, 2020, the revisions to the May 15, 2020, letter and authorized labeling included: (1) updating the authorized laboratories to include laboratories designated by Assurance Scientific Laboratories that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests, (2) add use of the Assurance COVID-19 Home Collection Kit to self-collect nasal swab specimens at home by individuals when determined to be appropriate by a healthcare provider, for use with the Assurance SARS-CoV-2 Panel, (3) added conditions of authorization specific to the addition of authorized laboratories designated by Assurance Scientific Laboratories, (4) update the healthcare provider and patient fact sheets to reflect language used in more recent authorization, (5) update the authorized labeling documents to include patient instructions and specimen accessioning standard operating procedures specific to the Assurance COVID-19 Home Collection Kit, and (6) remove use of the N2 target primer/probe set from the Assurance SARS-CoV-2 Panel.

<sup>3</sup> On June 3, 2021, the revisions to the August 19, 2020, letter and authorized labeling included: (1) updates to the intended use to remove use of the Assurance COVID-19 Home Collection Kit, update use of the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization and edits to reflect language used in more recent authorizations, (2) updates to the EUA Summary, Fact Sheet for Healthcare Providers and Fact Sheet to Patients to reflect the updated intended use and reflect language used in more recent authorizations, and (3) updating the Conditions of Authorization as a result of the change to the intended use and to reflect language used in more recent authorizations.

<sup>4</sup> On September 21, 2020, your request was granted via email to update the EUA Summary to add the results of the FDA SARS-CoV-2 Reference Panel.

<sup>5</sup> The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: <https://www.fda.gov/media/152406/download>

<sup>6</sup> The revisions to the June 3, 2021 letter and authorized labeling include: (1) addition of Promega Reliaprep TNA Extraction Kit and extraction-less QuickExtract DNA Extraction Solution for use with the Assurance SARS-CoV-2 Panel, (2) addition of the BioRad CFX Opus96, Applied Biosystems QuantStudio 3, and Analytik Jena qTower3/G thermocyclers for use with the Assurance SARS-CoV-2 Panel, (3) addition of the Apto-Gen One-step and AzuraQuant 1-step Probe NoRox qPCR master mixes for use with the Assurance SARS-CoV-2 Panel, (4) modification of the Assurance SARS-CoV-2 Panel assay from a singleplex format to a duplex format to enable simultaneous detection of the N and Rnase P genes, and (5) update of the “Assurance SARS-CoV-2 Panel SOP” name to “Assurance SARS-CoV-2 Panel SOP (RX and DTC)”.

<sup>7</sup> For ease of reference, this letter will use the term “your product” to refer to the Assurance SARS-CoV-2 Panel used for the indications identified above.

United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.<sup>8</sup>

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization Section of this letter (Section II), subject to the terms of this authorization.

### **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.<sup>9</sup>

### **II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

#### **Authorized Product Details**

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal or oropharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider.

Anterior nasal swab specimens may also be collected using the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization. Testing is limited to

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<sup>8</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

<sup>9</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

laboratories designated by Assurance Scientific Laboratories that are also certified under CLIA and meet the requirements to perform high-complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal, mid-turbinate nasal, nasopharyngeal or oropharyngeal swabs. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The Assurance SARS-CoV-2 Panel uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

Your product requires control materials or other authorized control materials (as may be requested under Condition H. below), that are described in the authorized procedures submitted as part of the EUA request.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the EUA Summary and the laboratory procedures submitted as part of the EUA request.

Your product is authorized to be accompanied with the labeling listed below, and as described in the EUA summary (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Assurance Scientific Laboratories - Assurance SARS-CoV-2 Panel
- Fact Sheet for Patients: Assurance Scientific Laboratories - Assurance SARS-CoV-2 Panel

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the “Assurance SARS-CoV-2 Panel SOP (RX and DTC)” (collectively referenced as “authorized labeling”) is authorized to be distributed and used by authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used as described within and used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized your product is authorized for the indication above.

### **III. Waiver of Certain Requirements**

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product.

### **IV. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

#### **Assurance Scientific Laboratories (You)**

- A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You must make your product available with the authorized labeling to authorized laboratories.
- C. You must make available on your website(s) the authorized Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

- D. You must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- E. You must ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- F. You must maintain records of the of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.
- G. You are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.
- H. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- I. You must evaluate the analytical limit of detection and assess traceability<sup>10</sup> of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- J. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Everlywell COVID-19 Test Home Collection Kit, and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).
- K. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).

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<sup>10</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- L. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

### **Authorized Laboratories**

- M. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- N. Authorized laboratories using your product must perform the test as outlined in the authorized labeling. Deviations from the authorized labeling, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to perform the test are not permitted.
- O. Authorized laboratories testing authorized specimens collected using the Everlywell COVID-19 Test Home Collection Kit with your product must follow any Specimens Accessioning protocols provided with the authorized Everlywell COVID-19 Test Home Collection Kit when accepting specimens for testing.
- P. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Q. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- R. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and you ([clientservices@assurancescientific.com](mailto:clientservices@assurancescientific.com)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- S. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.

### **Assurance Scientific Laboratories (You) and Authorized Laboratories**

- T. You and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

### **Conditions Related to Printed Materials, Advertising and Promotion**

- U. All descriptive printed matter, advertising and promotional materials, relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.
- V. No descriptive printed matter, advertising or promotional materials, relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.
- W. All descriptive printed matter, advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
  - This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
  - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

#### **V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.  
Acting Chief Scientist  
Food and Drug Administration

Enclosure